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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/828,716      | 08/30/2004  | Brian C. Case        | PA-5380-RFB         | 4764             |

9896 7590 05/24/2007  
COOK GROUP PATENT OFFICE  
P.O. BOX 2269  
BLOOMINGTON, IN 47402

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| EXAMINER |
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STEWART, ALVIN J

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3738

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| MAIL DATE | DELIVERY MODE |
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05/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/828,716

Applicant(s)

CASE ET AL.

Examiner

Alvin J. Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 2-12, 14, 15 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 13, 16, 17 and 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received..

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Claims 2-12, 14, 15, and 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/13/07.

Applicant's election without traverse of Species X reply filed on 03/13/07 is acknowledged.

Applicant's representative elected claims 15 and 18-20 were also elected but the examiner has withdrawn those claims because they belong to a different species. The above claims are referring to the embodiment of the species of Figures 9 and 11. See applicant's specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 22 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the lengths" in 7 & 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the second lateral edges" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the first portion" in line 16. There is insufficient antecedent basis for this limitation in the claim. The Examiner is not clear if the "first portion" is

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referring to the first proximal portion of the attachment pathway or is referring to a first portion of the distal portion. Clarification is required.

Regarding claims 13 and 28, the phrases: “the lumen of the bodily passage” and “the inner walls of the bodily passage” are they referring to part of the patient’s blood vessels? If yes, the Applicant has to enter functional language in from of that language in order to avoid possible 35 USC 101 rejection (claiming parts of human body).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13, 16, 17, 21-25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Moll et al US Patent 6,287,334 B1.

Moll et al discloses an artificial heart valve comprising a valve structure having a plurality of leaflets (6), the leaflets having proximal and distal portions, an inner edge traversing the passage, a first and second lateral edges (see attachment). The edges includes an attachment pathway, the pathway extends along the first and the second edges, each of the first and second lateral edges include a proximal attachment pathway portion (see attachment, the Examiner interpreted the opening used to connect element 6 with elements 8 as the attachment pathway. The opening of element 6, through the pointed end section 17, covers the internal and external surfaces of element 8).

Additionally, Moll et al discloses a support structure (10) comprising a series of proximal bends comprising commissural points and longitudinal attachment struts extending distally therefrom, the support structure further comprising a pair of distal attachment struts extending distally and circumferentially from the longitudinal attachment struts (see attachment). The lateral outer edges are attached proximally along the longitudinal attachment struts to form a extensive leaflet contact area and distally long the distal attachment struts which converge laterally and carry the bottom edge of each of the plurality of leaflets such that the prosthesis is adapted for forming a seal between the plurality of leaflets and the walls of the bodily passage and creating a large pocket at the base of each of the plurality of leaflets (see attachment).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mull et al US Patent 6,287,334 B1 in view of Park et al US Patent 6,669,724.

Mull et al discloses the invention substantially as claimed. However, Mull et al does not disclose a leaflet contact area that comprises 35-55 % of the length of the valve structure.

Park et al teaches a valve prosthesis comprising a plurality of leaflets having an internal wall wherein the amount of contactable or coactable area between the leaflets is between 33 to 55 % of the length of the whole valve system (see Figs. 2 & 4) for the purpose of efficiently avoiding retrograding flow (see col. 1, lines 38-45).


It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Mull et al reference with the larger coaptive area of the Park et al reference in order to efficiently avoiding retrograding flow.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

May 17, 2007.